K070568

510(K) SUMMARY

DIO Protem Implant Systems

MAY 25 2007

13-1. Submitter	DIO Department, DSI, Inc. 117 Kyo-Dong, Yangsan-City Kyungnam-Do, 626-210, South Korea Phone: 82-55-363-3401 Fax : 82-55-363-3404
13-2. US Agent / Contact Person	Kenny Lim 13340 E. Firestone Blvd. Suite J Santa Fe Springs, CA 90670 Phone : 562-404-8466, Fax : 562-404-2757
13-3. Date Prepared	February 09, 2007
13-4. Device Name	DIO PROTEM IMPLANT SYSTEMS
13-5. Classification Name	Endosseous Dental Implant System
13-6. Device Classification	Class II Dental Devices panel 21 CFR ξ 872.3640 Regulation Number:
13-7. Predicate Devices	INTERMEZZO ™ IMPLANT SYSTEM
13-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

13-9. Device Description

DIO Protem Implant System is a root-form threaded dental implant made of titanium alloy. The implant is produced by machining process, followed by grit blasting and cleaning. It is available in diameters 2.0 and 2.5mm, and lengths from 8mm to 14mm. It is placed via one stage surgery and the functional loading can be from immediate to delay.

13-10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a capsule, and then put the capsule in a pet container, which is 45mm by 75mm, then sealed the pet container with PERFECSEAL CR27 1073B Coated Tyvek®. DIO Protem Implant Systems will be packaged.

13-11. Intended Use

DIO Protem Implant Systems is threaded one-piece implants designed for orthodontic one-stage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function. DIO Protem Implant System consists of single-stage, root-form dental implants. The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. DIO Protem Fixtures are to be removed within six to ten weeks after the surgery depending on a patient's bone condition. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.

13-12. Substantial Equivalence Comparison

TECHNOLOGICAL CHARACTERISTIC COMPARISON

	Subject Device	Predicate Device
Device Name	DIO DENTAL IMPLANT CO. LTD (DIO Protem Implant System)	Mega'Gen Co., Ltd. (Intermezzo ™ Implant System) **K051018**
Intended Use	Identical to predicate devices	Immediate Provisional Implants are placed in upper or lower jaw to function for six to ten weeks temporary use period and then, removed. The implants can be placed quickly and efficiently, with little or no discomfort or inconvenience to the patient.
Material	Titanium alloy	Commercially pure titanium GR. 3 (ASTM-F-67)
Screw Threads	YES	YES
Implant Thread Diameter (mm)	2.0 and 2.5	1.6, 2.0, 2.5, 3.1
Lengths(mm)	8-14 mm	10.0, 13.0, 15.0
Surface Treatment	Machined	Machined
Sterilized	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2007

DIO Department, DSI, Incorporated
C/O Mr. Kenny Lim
Consultant/U.S Agent
Kodent, Incorporated
13340 E. Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K070568
Trade/Device Name: DIO Protem Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 23, 2007
Received: March 3, 2007

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

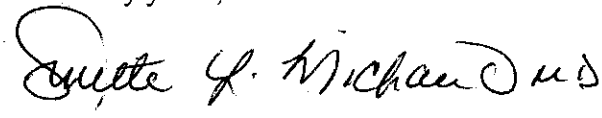
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K070568

Device Name: DIO Protem Implant System

Indications For Use:

The DIO Protem Implant Systems are intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

Prescription Use X AND/OR _____ Over – The-Counter Use
(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Kevin Mulloy for M&R

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K070568